

**DECISION MEMORANDUM FOR ITALY**  
**INDIVIDUAL SANITARY MEASURE**  
**EXEMPTION FROM 9 CFR 430.4 FOR DRY-CURED BONE-IN HAM**  
**March 29, 2011**

**ISSUE:**

Italy has requested that the Food Safety and Inspection Service (FSIS) review an individual sanitary measure that requests FSIS 1) determine that the skin and sugna<sup>1</sup> of Italian dry-cured bone-in hams are immediate containers and 2) reclassify these hams from ready-to-eat (RTE) to not RTE thereby exempting them from the requirements of 9 CFR 430.4.

**BACKGROUND:**

On June 21, 2010, representatives from the government of Italy (GOI) met with representatives from the Food Safety and Inspection Service (FSIS) to consider 1) that the skin and sugna constitute an immediate container for bone-in dry cured hams and that the hams be reclassified from RTE to not RTE hams exempt from 9 CFR 430. It should be noted that these hams were designated as RTE based on the FSIS 2009 audit of the Italian Food Safety System. The GOI sent a follow-up letter dated August 8, 2010, to FSIS. Finally, at the request of FSIS, the GOI sent a letter dated January 26, 2011 requesting an equivalence evaluation for an individual sanitary measure regarding these two issues. As a result, in the individual sanitary measure request, the GOI presented two processes for evaluation. One is when the dry-cured bone-in hams are cured in one establishment and shipped to another establishment for deboning and slicing. The other is when the dry-cured bone-in hams are exported to the U.S.

**DOCUMENT REVIEW:**

- 1) Definition of an immediate container per ask FSIS (9 CFR 301.2).
- 2) Definition of ready-to-eat products per ask FSIS (9 CFR 430.1).
- 3) Correspondence between the Ministry of Health and FSIS (April 22, 2009).
- 4) Letter from FSIS to Italy dated December 4, 2009 describing results of the August 26 to September 29, 2009, audit of the Italian Food Safety Inspection System.
- 5) Detailed explanation of the topic as provided in the June 21, 2010 meeting with the Italian officials.
- 6) *Validation of the Manufacturing Process of Italian Dry-Cured Ham (Prosciutto) for the Inactivation of Listeria monocytogenes and Salmonella spp.*, Silvana Baruti *et.al.* (March 6, 2006).
- 7) Photographic Documentation of Deboning Process; Details of Exemption Request
- 8) Italian letter dated August 8, 2010, to FSIS.
- 9) Several other articles demonstrating the finding of *Lm* in dry-cured-bone-in hams prepared by OPHS.
- 10) Italian letter dated January 25, 2011, requesting an individual sanitary measure for the processing of dry-cured-bone-in hams.

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<sup>1</sup> Sugna (SOON-yah) is rendered pork fat, which is spread over the exposed part of the ham (hip and hock joints). Usually the fat is mixed with spices like salt and pepper, but each establishment has their own special mix and proportions.

## EQUIVALENCE CRITERIA

The general criteria for determining the equivalence of an alternative meat, poultry, or egg products inspection program are as follows:

1. Does the program meet all U.S. Department of Agriculture (USDA) requirements for the export of meat and poultry and meat, poultry, and egg products to the U.S.?
2. Does the program afford American consumers the same level of public health protection provided by USDA domestic meat inspection?

## EQUIVALENCE EVALUATION:

In response to issues raised by the Italian Chief Veterinary Officer (CVO) in his letter dated January 26, 2011, for the skin and sugna to be considered an immediate container and an exemption to 9 CFR 430 for dry-cured hams, here are the FSIS responses.

First, Italy has requested that FSIS honor 9 CFR 94.17 that does not prohibit dry-cured ham from being imported into the United States which meet the animal disease requirements. Nine (9) CFR 94.17 is an Animal and Plant Health Inspection Service (APHIS) regulation that outlines conditions that must be met for dry-cured pork products to enter the U.S. from restricted areas. Nine (9) CFR 94.17 is not a public health regulation but it does specifically refer to section (e) with a reference to <sup>16</sup> which states, “<sup>16</sup>As a condition of entry into the United States, pork and pork products must also meet all of the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*).

Second, Italy requested that FSIS consider skin and sugna to be an immediate container which implies the product is not post-lethality exposed or subject to the regulatory requirements of 9 CFR 430. Nine (9) CFR 301.2 defines an immediate container as the receptacle or other covering in which any product is directly contained or wholly or partially enclosed. The skin and sugna do not meet the FSIS definition of an immediate container since the skin is an integral component of the product, both skin and sugna are edible, and internal meat tissues could be contaminated when washing or removing the surface components during deboning or slicing of the hams. Additionally, the exterior of the product can easily become contaminated with pathogens, such as *Lm*, resulting in an insanitary condition and cause adulteration of RTE products. Moreover, exterior contamination, such as when packaging product, could lead to insanitary conditions when handling other products. The FSIS has no data on the permeability of the skin and sugna to *Lm*. Regardless of permeability, the FSIS method used to test for *Lm*, *Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Egg, and Environmental Samples*,<sup>2</sup> MLG 8.07 8.5.1, requires that when product is sampled, intact retail packages (immediate containers) must be disinfected at the incision sites immediately prior to sampling. Appropriate disinfectants include but are not limited to ca. 3% hydrogen peroxide, ca. 70% ethanol or ca. 70% isopropanol. Additionally if the package does not appear to be clean, the package must be scrubbed gently using soapy water and rinsed thoroughly. Then the packaging is aseptically pulled away to expose the product for sampling. The use of these disinfectants applied to the skin and sugna of dry-cured bone-in hams would render the entire product unusable for microbiological testing and also render the product adulterated.

<sup>2</sup> [http://www.fsis.usda.gov/PDF/MLG\\_8\\_07.pdf](http://www.fsis.usda.gov/PDF/MLG_8_07.pdf)

Next, Italy requested that FSIS reconsider its designation of dry-cured bone-in hams as ready-to-eat (RTE) subject to 9 CFR 430.4 (a)(2) that was determined by FSIS during the August 26 to September 29, 2009, audit of the Italian Food Safety Inspection System (see tab 4, December 4, 2009 letter and audit report). It is the Italian position that these products are not RTE (NRTE). There is no standard of identify that specifies dry-cured bone-in hams as RTE. If the manufacturer determines the status of the product as NRTE, the product must be labeled with safe handling instructions. This product label must contain instructions to signify, for food safety reasons, that the product is required to be thoroughly cooked prior to consumption. In the absence of this clear declaration the products would be considered RTE. The FSIS has declared *Lm* to be an adulterant<sup>3</sup> and, as such, has implemented a zero tolerance policy for this pathogen in RTE meat products regardless of whether the process supports growth of this pathogen<sup>3</sup> or not. The scientific publication that was submitted by Italy specifically points out and states that dry-cured bone-in hams are RTE.<sup>4</sup> The FSIS has found scientific articles that demonstrate that *Lm* has been isolated from dry-cured bone-in hams and products derived from the hams.

Italy's last request was for FSIS to consider the RTE status of two processes for dry-cured bone-in hams separately. These two processes are 1) when dry-cured bone-in hams are shipped to another establishment for further processing (deboning and finishing or slicing) and 2) when these hams are exported as the unfinished product without further processing. In the first case, Italy requested that the hams not be considered RTE and, therefore, exempt from 9 CFR 430.4 as these products will be subject to a post lethality treatment. Then these products must be labeled for further processing in a Federal establishment. In addition, FSIS Directive 10,240.4, VERIFICATION PROCEDURES FOR CONSUMER SAFETY INSPECTORS FOR THE *Listeria monocytogenes* (*Lm*) REGULATION AND *Lm* SAMPLING PROGRAMS, Attachment 2<sup>5</sup> states that when product is shipped to another establishment for post lethality processing, 9 CFR 430.4 still applies if the product is post lethality exposed, which also applies to these products. In the second case, Italy states that 1% of dry-cured bone-in hams are produced for export to the U.S. without further processing. Italy makes no specific request to the RTE status of these hams. These hams have the potential to reach the consumer without further processing. Since FSIS has already determined that the current status of Italian dry-cured bone-in hams are RTE, these hams are also post-lethality exposed, and therefore subject to 9 CFR 430.4 at the establishment producing them and reinspection for *Lm* at the U.S. port-of-entry where the hams are subject to the FSIS zero tolerance policy. This situation could change should Italy declare these products NRTE and properly labels the product.

#### RECOMMENDATIONS:

The reviewers found that the Italian requests to determine that the skin and sugna are immediate containers and to reclassify dry-cured bone-in hams from RTE to NRTE would not meet the established criteria addressed in 9 CFR 310.1, 430.1, 430.4, or FSIS Directive 10,240.4 and therefore does not meet all USDA requirements for the export of meat and poultry and meat, poultry, and egg products to the U.S. Nor would the request afford the U.S. consumer with the same level of public health protection provided by

<sup>3</sup> EQUIVALENCE CRITERIA (2010) Control Program for *Listeria monocytogenes* in Ready-to-Eat Products

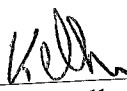
<sup>4</sup> Validation of the Manufacturing Process of Italian Dry-cured Ham (Prosciutto) for the Inactivation of *Listeria monocytogenes* and *Salmonella spp.*, Silvana Baruti, et. al.

<sup>5</sup> <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4Rev2.pdf>

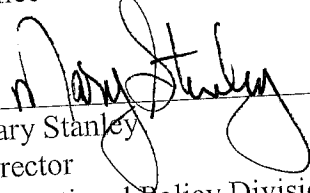
USDA domestic meat inspection of dry-cured bone-in ham. Therefore, this request that skin and sugna be determined to be an immediate container and to reclassify dry-cured bone-in ham as NRTE should not be granted.

Actions that could modify FSIS's recommendation would be to 1) address the exterior contamination of the Italian dry-cured bone-in hams if they are not going to be encased inside protective packaging and 2) properly label the product if Italy wants to designate their product as NRTE. The product would be exempt from 9 CFR 430; however, such product must bear a safe handling instruction that clearly conveys that the product must be cooked prior to consumption. In the absence of such a designation, the product is RTE and is subject to 9 CFR 430.

**APPROVAL:**

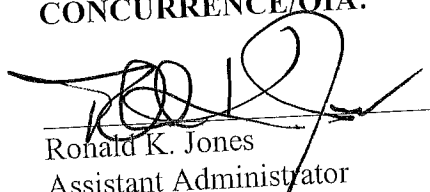
  
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Andreas Keller  
Director  
International Equivalence Staff  
Office of International Affairs, FSIS

Date 3.30.11

  
\_\_\_\_\_  
Mary Stanley  
Director  
International Policy Division  
Office of Policy and Program Development

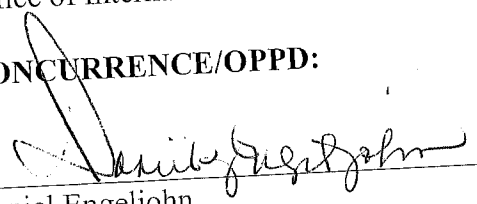
Date 4 April 2011

**CONCURRENCE/OIA:**

  
\_\_\_\_\_  
Ronald K. Jones  
Assistant Administrator  
Office of International Affairs, FSIS

Date 4-12-2011

**CONCURRENCE/OPPD:**

  
\_\_\_\_\_  
Daniel Engeljohn  
Assistant Administrator  
Office of Policy and Program Development, FSIS

Date 4.15.11